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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,104	04/28/2005	Yong Kwee	053466-0401	5920

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,104	KWEE ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,12,14 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,12,14 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibits A and B*.

DETAILED ACTION

RE: Kwee et al.

1. Applicant's species election with traverse of SEQ ID NO.16 in the reply filed on 2/25/2008 is acknowledged. The traversal is on the ground(s) that SEQ ID NO.17 is part of SEQ ID NO.16 and there is no burden to search both sequences. This is found persuasive. The requirement for species election set forth in the office action mailed on 1/24/2008 is hereby withdrawn in view of applicant's amendment to the claims and persuasive arguments. The SEQ ID NO.16 and 17 are examined together.

2. Claims 1, 3, 12, 14 and 23 are pending. New claim 23 has been added after the non-final office action mailed on 6/19/2007. Claims 2, 4-11, 13 and 15-22 have been cancelled.

3. Claims 1, 3, 12, 14 and 23 are under examination.

Objections Withdrawn

4. The objection to claims 1 and 12-14 because the claims contain non-elected invention, i.e. HM1.24 DNA and HM1.24 RNA is withdrawn in view of applicant's amendment to the claims.

5. The objection to claim 12 because of a typographical error is withdrawn in view of applicant's amendment to the claims.

Rejections Withdrawn

6. The rejection of claims 1, 3, 12 and 14 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Porgador et al. (J. Exp. Med., 1995, 182: 255-260, IDS) is withdrawn in view of the new grounds of rejections.

Response to Arguments

Claim Rejections - 35 USC § 112, 1st paragraph

7. The rejection of claims 1, 3, 12, 14 and new claim 23 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigen-specific dendritic cell pulsed by an HM1.24 protein or an HM1.24 peptide, does not reasonably provide enablement for a cancer vaccine containing as an active ingredient an antigen-specific dendritic cell pulsed by an HM1.24 protein or an HM1.24 peptide is maintained.

The response states that the present invention is directed to a cancer vaccine, and not a vaccine in the sense of a preventative measure. The cancer vaccine is usually used for the treatment of cancer.

Applicant's arguments have been carefully considered but are not persuasive. MPEP 2111[R-5] states that during patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification. Because the definition for the term "vaccine" is a preparation for preventing a disease, the invention is directed to a composition for preventing a cancer. As indicated in the previous office action, since no material has been found to date that has been shown to

or would be expected to prevent cancer, and there is no working example, prior art, or any evidence that would provide the skilled artisan with any predictable guidance to use the claimed invention, it would be reasonable to conclude the claimed invention is not enabled. For these reasons, the rejection is proper and therefore maintained.

New Grounds of Objections and Rejections

Claim Objections

8. Claim 14 is objected to because of the following informalities: claim 14 is a duplicate of claim 12. Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27).

Treon et al. teach that an alternative strategy of targeted therapy is to generate active specific immunity against the patient's tumor. Treon et al. teach in addition to presenting myeloma associated peptides, the dendritic cells can also be pulsed with

whole tumor antigen, naked DNA or whole tumor RNA for treating multiple myeloma (MM) (see page 604, left column). Treon et al. teach that HM1.24 is expressed on MM patient plasma cells and myeloma cell lines (see page 601, last paragraph). Treon et al. teach that HM1.24 is one of the typical candidate targets for antibody-mediated therapy of MM (see page 599, left column line 3).

Treon et al. do not specifically describe dendritic cells pulsed with HM1.24 antigen. However, these deficiencies are made up for in the teachings of Ohtomo and Chiriva-Internati.

Ohtomo et al. teach that HM1.24 antigen has been identified as a surface molecule preferentially expressed on terminally differentiated B cells and its overexpression is observed in multiple myeloma (MM) cells (see abstract). Ohtomo et al. that the HM1.24 antigen is expected as a most potent target molecule for antibody-based immunotherapy for multiple myeloma (see abstract). Ohtomo et al. teach how to make soluble HM1.24 antigen (see page 584, last paragraph).

Chiriva-Internati et al. teach that pulsing dendritic cells via an adeno-associated viral vector/HM1.24 recombinant generates rapid, significant cytotoxic T lymphocytes and interferon activity against multiple myeloma and synthetic HM1.24-positive autologous targets (see abstract). Chiriva-Internati et al. teach that HM1.24 may be an effective antigen for targeting MM (see abstract)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make dendritic cells pulsed with HM1.24 antigen for treating multiple myeloma in view of the teachings of Treon, Ohtomo and Chiriva-

Internati. One would have been motivated to do so because Treon et al. teach that generating active specific immunity against the patient's tumor is an alternative strategy for treating MM, both Treon and Ohtomo teach that HM1.24 is a myeloma specific tumor antigen, and Chiriva-Internati et al. have shown that dendritic cells pulsed with a vector encoding HM1.24 antigen generates rapid, and significant cytotoxic T lymphocytes. One of ordinary skill in the art would have a reasonable expectation of success to make dendritic cells pulsed with HM1.24 antigen for treating MM because Chiriva-Internati et al. have shown that dendritic cells pulsed with a vector encoding HM1.24 antigen generates rapid, and significant cytotoxic T lymphocytes, and the method of making dendritic cells pulsed with a tumor antigen is known in the art as shown by Treon et al.

For this rejection, the intended use i.e. a cancer vaccine is not given patentable weight.

11. Claims 1, 3, 12, 14 and new claim 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27), further in view of WO 200177362 (Pub. Date: 10/18/2001, IDS), as evidence by Porgador et al. (J. Exp. Med., 1995, 182: 255-260, IDS).

The teachings of Treon, Ohtomo and Chiriva-Internati have been set forth above as they apply to claims 1, 12 and 14 (see paragraph 10 above).

Treon, Ohtomo and Chiriva-Internati do not teach pulsing dendritic cells with the soluble HM1.24 that is SEQ ID NO.16 or 17. However, these deficiencies are made up for in the teachings of WO 200177362 and Porgador et al.

WO200177362 teaches a process whereby a highly purified soluble HM1.24 antigen protein (the extracellular domain of HM1.24 antigen) can be produced at a high efficiency (see abstract). The soluble HM1.24 antigen disclosed on pages 85-86 is 100% identical to the instant SEQ ID NO.16 (see Exhibit A). The soluble HM1.24 antigen disclosed on page 86-87 is 100% identical to the instant SEQ ID NO.17 (see Exhibit B).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make dendritic cells pulsed with the soluble HM1.24 antigens of WO200177362 for treating multiple myeloma in view of the teachings of Treon, Ohtomo, Chiriva-Internati, and WO200177362. One would have been motivated to do so because the soluble HM1.24 antigens of WO200177362 can be prepared recombinantly with high purity at high efficiency. Moreover, for presenting a tumor surface antigen to T cells, the dendritic cells can be pulsed by a whole tumor antigen, or peptides thereof, as evidenced by Porgador. Porgador et al. teach a method of making dendritic cells pulsed with class I-restricted peptides. One of ordinary skill in the art would have a reasonable expectation of success to make dendritic cells pulsed with soluble HM1.24 antigens of WO200177362 for treating multiple myeloma because WO200177362 teaches how to make such soluble HM1.24 antigens.

For this rejection, the intended use i.e. a cancer vaccine is not given patentable weight.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
4/17/08